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This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Products containing chlorhexidine gluconate or products containing chlorhexidine hydrochloride (OTC drugs)

October 17, 2017

Non-proprietary name

Products containing chlorhexidine gluconate or products containing chlorhexidine hydrochloride (OTC drugs)

Safety measure

Precautions should be revised in the package insert.

In the When not to use the product section, the following text should be added (underlined parts are revised):

<u>This product should not be used in the following persons</u>: <u>Patients who have had an allergic symptom to this drug, its ingredients, or chlorhexidine</u>.

In the Consultation section, the following text should be added (underlined parts are revised):

If the following symptoms are observed after using this drug, these may be adverse reactions, so immediately discontinue the use, and show this document to your physician, pharmacist, or registered sales person for a consultation.

The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid:

<u>Shock (anaphylaxis):</u> <u>Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing</u> <u>Pharmaceuticals and Medical Devices Agency</u> Office of Safety I 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

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difficulties, palpitations, and clouding of consciousness may occur immediately after use.

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